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The Honorable Colm F. Connolly
United States District Court
for the District of Delaware
844 North King Street
Wilmington DE 19801

PUBLIC VERSION

Re: *Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 18-651 (CFC);
Vanda Pharmaceuticals Inc. v. Apotex Inc. et al., C.A. No. 18-689 (CFC);
Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc. et al., C.A. No. 18-690 (CFC)

Dear Judge Connolly:

Plaintiff submits this response regarding the parties' protective order dispute. The dispute centers on Defendants' unusual request for the Court to impose a contested—but selective—"FDA bar" in the protective order. Vanda opposes the imposition of this bar. (**Exhibit 1**). To be clear, the parties agree that the opposing party's confidential information may not be used for any purpose other than this litigation. Defendants, however, seek an additional prophylactic bar, preventing both in-house and outside counsel with access to an adverse party's confidential information from any involvement in communications with FDA regarding "approval requirements" for formulations of the drug tasimelteon, the drug at issue in this litigation. Contrary to Defendants' assertion, such FDA bars proactively restricting conduct to avoid accidental disclosure or use of confidential information are not a standard feature of Hatch-Waxman litigation. Indeed, Defendants do not cite a single instance of a court in this District having imposed an FDA bar over the objection of a party. Here, Defendants have failed to meet their burden to demonstrate the necessity of an FDA bar. Defendants' request should be rejected.

Background. Vanda is a small company with only two products, both of which have been involved in Hatch-Waxman litigation in this District. In the prior cases regarding Vanda's Fanapt® product, the protective order did not include an FDA bar. Here, Vanda, as the Plaintiff, provided the initial draft of the protective order without an FDA bar, consistent with its previous cases. Defendants responded with a proposed bar that would encompass any communication with FDA regarding "approval requirements" for tasimelteon; effectively the provision they now seek. "Approval requirements" could, thus, relate to the approval of Defendants' products, or a "Citizen's Petition" relating to FDA standards for approval. But Defendants' proposal would exempt any "work to obtain approval of," or amendments to, a party's NDA or ANDA. Vanda did not agree to these terms, but offered a compromise whereby the parties' counsel would be

precluded from all FDA communications if they accessed another party's confidential information. Defendants refused this compromise.

As such, Defendants seek what is essentially a "one way" FDA bar that would allow their in-house and outside counsel to view confidential information related to Plaintiff's Hetlioz® product while still participating in seeking FDA approval of Defendants' generic versions, but would prevent Plaintiff's counsel from filing or responding to FDA "Citizen's Petitions" relating to approval requirements—including responding to a Citizen's Petition already filed by a public advocacy group. Def's Ltr. at 3 & n.2. As Defendants admit, when presented with a "two way" bar that would also apply to its counsel who have access to Vanda's information, Defendants' concerns shifted and they were unwilling to agree to the restrictions they now seek to place on Vanda. Defendants' "one way" bar thus does not appear to mitigate a serious concern with disclosure or harm to Defendants. Instead, such a bar would impede Vanda's ability to work with its counsel on Citizen's Petitions while preserving Defendants' freedom to have their litigation counsel discuss approval requirements with FDA in the context of their ANDAs. Defendants' concern for the burdens that an FDA bar would place on themselves, and their stated reason for why the Court should approve an exemption to the FDA bar, demonstrate exactly why no FDA bar is warranted in the first place.

Argument. To obtain any protective-order provision, the requesting party must demonstrate "good cause" pursuant to Fed. R. Civ. P. 26(c). Defendants erroneously cite Federal Circuit law relating to a patent prosecution bar, *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373 (Fed. Cir. 2010), for the proposition that a bar is warranted if its omission would pose an unacceptable risk of inadvertent disclosure. An FDA bar, however, is not patent-specific, and Third Circuit law should govern. Defendants must therefore demonstrate that they will suffer "clearly defined, specific and serious injury" absent an FDA bar, a showing for which "broad allegations of harm are not sufficient." *Shingara v. Skiles*, 420 F.3d 301, 306 (3d Cir. 2005). Defendants have not articulated a clearly defined, serious injury. Indeed, their letter fails to articulate any particularized harm that would arise from the absence of an FDA bar. Nor have they even met the Federal Circuit's standard by showing an unacceptable risk of disclosure.

In fact, courts in this District have regularly rejected disputed FDA bars in light of the proponents' failure to identify the clearly defined, serious injury that would result in the absence of a prophylactic FDA bar and where, as here, the protective order already precluded the use of confidential information in such contexts. *See Cephalon, Inc. v. Impax Labs., Inc.*, No. 11cv1152 (SLR), D.I. 56, at 2 (D. Del. June 29, 2012) (**Exhibit 2**) (finding that defendants had not provided "an explanation of what circumstances would allow plaintiffs' counsel to be interfacing with the FDA about a competitor's ANDA, resulting in a risk of an inadvertent disclosure of confidential, litigation-generated information"); *Eurand, Inc. v. Mylan Pharm. Inc.*, No. 8cv889 (SLR), D.I. 71, at 2 (D. Del. June 23, 2009) (**Exhibit 3**) ("Unlike patent prosecutions, . . . interfacing with the FDA is an administrative task undertaken after the creative process has been completed. I cannot fathom (and defendants have failed to illuminate the issue with specific examples) how the risk of an inadvertent disclosure to the FDA in an ANDA context warrants the substantial burden such a bar would impose."); *Reckitt Benckiser Pharm. Inc. v. Par Pharm., Inc.*, No. 13cv1461 (RGA), D.I. 48, at 5-7 (D. Del. Apr. 10, 2014) (**Exhibit 4**) ("I do not believe that the proposed FDA bar reasonably reflects the risk presented by the disclosure of proprietary competitive information."); *Mayne Pharm. Int'l v. Merck & Co., Inc.*, No. 15cv438 (LPS), D.I.

47, at 13 (D. Del. Mar. 17, 2016) (**Exhibit 5**) ("[A]ll of the examples that the plaintiff points to for what it is concerned with are in reality intentional acts that are already prohibited under the agreed-upon portions of the protective order. So I don't see anything to be accomplished by the inclusion of the FDA bar."); *Alza Corp. v. Par Pharm. Inc.*, No. 13cv1104 (RGA), D.I. 78, at 26 (D. Del. Dec. 17, 2013) (**Exhibit 6**) ("[T]he risk of an inadvertent disclosure is so minimal . . . . [T]he burden that you have to show that there should be a bar that extends to the FDA proceedings, I don't think you've met that, so I'm going to deny."). As noted above, Defendants cite no case, and we are aware of none, where an FDA bar was imposed over a parties' objection. Defendants cite only uncontested bars and a New Jersey opinion in which both parties agreed to an FDA bar in principle.

Defendants' justification for an exemption for their own counsel is the need to ensure consistency in positions they take before this Court and FDA. That need only underscores the burden of having any FDA bar. While Defendants cite Citizen's Petitions as the reason an FDA bar is needed, they never explain that reason or effectively distinguish Citizen's Petitions from the work Defendants' counsel would be permitted to perform in working on ANDAs under Defendants' requested one-way FDA bar. They simply quote *Deutsche Bank*'s general rationalization for prophylactic bars (in the patent prosecution context) without explaining why such a prior restraint on only certain types of FDA communications is necessary here. Defs' Ltr. at 3. In fact, patent prosecution is very different: the concern in *Deutsche Bank* was that a lawyer seeking to extend a client's monopoly through patent prosecution would, if exposed to an adversary's confidential information, be unable to avoid having such information influence the drafting of patent claims that might cover the adversary's product.

A Citizen's Petition, by contrast, invokes a person's First Amendment right to petition the government and, as it relates to FDA, to raise concerns that affect the public interest. Limitations on any client's right to use the counsel of its choice to petition the government should be viewed with concern. In addition, FDA can delay an ANDA application in response to a Citizen's Petition only if FDA determines that the delay is "necessary to protect the public health." 21 U.S.C. § 355(q). Further, the one Citizen's Petition Defendants cite was not filed by Vanda, but by a public-advocacy group. Defs' Ltr. at 3 & n.1. Defendants' FDA bar could preclude Vanda's counsel from responding to that Citizen's Petition simply because that counsel had seen Defendants' confidential information, regardless of whether the confidential information had anything to do with the Citizen's Petition or Vanda's response to it. Moreover, Congress has authorized FDA to "dismiss citizen petitions summarily in order to prevent pharmaceutical companies from using this process to unlawfully extend their monopolies." *Roxane Labs. Inc. v. SmithKline Beecham Corp.*, 2010 WL 331704, at *1 n.2 (E.D. Pa. Jan. 26, 2010) (citing 21 U.S.C. § 355(q)).

Defendants provide no basis for why good cause supports the need for an FDA bar in this case. Nor do they provide a basis for why there would be no risk of disclosure by Defendants' counsel privy to Vanda's confidential information in the course of working on their clients' ANDAs, but that there would be an unacceptable risk of inadvertent disclosure with regard to Citizen's Petitions. Defendants' refusal of a balanced FDA bar demonstrates that their concern with the inadvertent use of confidential information only goes in one direction and is not grounded in a concrete concern. Such a basis fails to rise to the standard necessary for the Court to institute an FDA bar. Defendants' request should therefore be denied.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF:ncf
Enclosures
cc: Clerk of Court (by hand delivery w/enclosures)
All Counsel of Record (by e-mail w/enclosures)